

Application No. 09/763,106
Amendment Dated July 23, 2004
Reply to Office Action of August 27, 2003

REMARKS/ARGUMENTS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

New claims 19-23 have been added. Claim 19 is supported by the specification, for example, at page 3, in the fourth paragraph on the page, wherein it is taught that the invention relates to "bath * * * preparations," which a person having ordinary skill in the art would understand are intended to be used in bathing. Claim 20-23 are based on claims 12 and 14-17, respectively. Applicants do not believe that the amendment introduce any new matter.

Rejections under 35 U.S.C. 112, first paragraph

Claims 7 and 12 stand rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. The Examiner premises her rejection on the Wands factors. These factors include:

- 1) The nature of the invention
- 2) The state of the prior art
- 3) The relative skill of those in the art
- 4) The predictability or unpredictability of the art
- 5) The breadth of the claims
- 6) The amount of direction or guidance presented
- 7) The presence of absence of working examples
- 8) The quantity of experimentation necessary

Page 6 of 15

Application No. 09/763,106
Amendment Dated July 23, 2004
Reply to Office Action of August 27, 2003

Applicants point out a conclusion of enablement must be made on the evidence as a whole. See *In re Wands*, 8 USPQ2d at 1404; See also MPEP §2164.01(a).

Regarding 1), the Examiner appears to treat the instant claims as directed to a pharmacological treatment. Applicants point out the present invention is not for a pharmacological treatment, but rather for a "method for preventing or reducing the attachment of a lauryl ether sulfate to human skin during a *washing process*".

Regarding 3) and 4), the Examiner concedes the level of skill in the art is high and also there is high predictability in the art. Therefore, a person of ordinary skill in the art would need less information to practice the present invention.

Regarding 5), Applicants submit the instant claims do not encompass any and all ingredients. The results of the claimed method must be to fulfill the purpose of "preventing or reducing the attachment of a lauryl ether sulfate to human skin during a *washing process*". Therefore, the instant claims cannot require any or all ingredients and amounts thereof that do not allow the purpose to be fulfilled.

Regarding 6), the Examiner cannot find guidance in the specification for "preventing" but concedes to "reducing". It is respectfully not seen how the Examiner can find "reducing" but not "preventing". Applicants point to the specification at page 4, lines 10-13 which discusses "preventing" and "reducing" side-by-side. Applicants would remind the Examiner that the

Application No. 09/763,106
Amendment Dated July 23, 2004
Reply to Office Action of August 27, 2003

allegations in the specification must be accepted as true in the absence of reasonable doubts supported by sound technical reasoning or evidence. *In re Marzocchi et al.*, 169 USPQ 367, 369 (CCPA 1971). Applicants would also inform the Examiner that *In re Marzocchi et al.* is the controlling case, notwithstanding *In re Dreshfield*, *In re Riat et al.*, and *In re Barr*. Accordingly, the allegation of "preventing" has to be accepted as true, unless the Examiner comes forth with evidence or sound scientific reasoning tending to cast doubt on the Applicants' assertion that the attachment of a lauryl ether sulfate to human skin can be prevented during a washing process. The Examiner has not advanced any evidence or sound scientific reasoning why it should be impossible to prevent the attachment of a lauryl ether sulfate to the claims. As a result, the allegation must be accepted.

Regarding 7), 35 U.S.C. 112, first paragraph, does not require working examples and therefore the presence or absence of working examples is not fatally defective.

Regarding 8), the Examiner notes that a person of ordinary skill in the art would be burdened with undue "painstaking experimentation study". But the fact remains that the experimentation only requires that a person of ordinary skill in the art:

- 1) Make the formulations and
- 2) Test whether the application of lauryl ether sulfate and one or more anionic surfactants prevents or reduces the attachment of lauryl ether sulfate to human skin during the washing process.

The Examiner concedes the level of skill in the art is high and the degree of predictability in the art is high. Therefore, a person of ordinary skill in the art should have no problem carrying

Application No. 09/763,106
Amendment Dated July 23, 2004
Reply to Office Action of August 27, 2003

out the testing and making extrapolations from the various tests. As the Court in *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), explained, “[e]nabling is not precluded by the necessity for some experimentation such as routine screening.” Further, on the same page, they quoted with approval the following quote from *In re Jackson*, 217 USPQ at 807 (POBA 1982):

“The test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction the experimentation should take.

[Emphasis added.]”

The Examiner here has not shown that any of the testing is other than straight-forward, conventional and routine, and accordingly any required experimentation is *not* undue.

In view of the foregoing, Applicants submit that the Examiner would be fully justified to reconsider and to withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is, therefore, earnestly solicited.

Rejections under 35 U.S.C. 102

The Examiner rejected claims 7 and 12-17 under 35 U.S.C. 102(b) as being anticipated by Mager et al. (JP 09-301834). The Examiner found Mager to exemplify a hair washing agent

Application No. 09/763,106
Amendment Dated July 23, 2004
Reply to Office Action of August 27, 2003

comprising 1-14% N-acylglutamate and 1-14% sodium lauryl ether sulfate. In response, Applicants have checked the examples and none of them show both the N-acylglutamate and the sodium lauryl ether sulfate. Indeed, it can be seen by the cited abstract that the formulation does *not* have to contain either the N-acylglutamate or sodium lauryl ether sulfate. They are *optional* ingredients. Therefore, the reference teaches a washing agent which comprises:

- a) A half ester of ethoxylated sulfo-succinic acid of formula I and/or N-acylglutamate of formula II
- b) An amphoteric betaine surfactant
- c) Sodium lauryl ether sulfate and/or sodium myristyl ether sulfate and
- d) Cationic cellulose.

Applicants point out the location of "and/or" makes clear that neither sodium lauryl ether sulfate nor N-acylglutamate are necessary components. Thus, for example, the reference includes the following formulation, which does not contain either N-acylglutamate or sodium lauryl ether sulfate:

- a) A half ester of formula I
- b) An amphoteric betaine surfactant
- c) Sodium myristyl ether sulfate and
- d) Cationic cellulose.

Clearly, such formulation does not contain either N-acylglutamate or sodium lauryl ether sulfate. Consequently, it is not the case here that Mager anticipates the instant claims.

The Examiner takes the position the application of the preparation to hair would

Page 10 of 15

Application No. 09/763,106
Amendment Dated July 23, 2004
Reply to Office Action of August 27, 2003

inherently result in its application to the scalp. Applicants submit this is not necessarily the case, and respectfully request that the Examiner document her position. For many applications, a person is bent over a sink, in a salon for example, where the sole purpose is for the remainder of the body to not be in contact with the shampooing agents. Accordingly, it is possible for hair to be washed without wetting the scalp. Moreover, Applicants submit that the Examiner has not established a *prima facie* case of inherency. As pointed out by the Board of Patent Appeals and Interferences in *Ex parte Levy*, 17 USPQ2d 1461, 1463-1464 (BPAI 1990):

"[T]he initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention rests upon the Examiner. * * * In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. [Emphasis in original.]"

Applicants submit that the Examiner has not discharged this initial burden. Since it is possible for the scalp to not be affected, it is also possible that application to hair does not necessarily result in the application to the scalp.

Applicants would point the Examiner to the first paragraph on page 5 of the Office Action. The Examiner discusses the "instantly claimed *product*". In this, the Examiner confuses the issue as the instant claims are drawn to a *method* and novelty of the method depends on whether the method has been practiced before, i.e., whether anyone has applied the composition

Application No. 09/763,106
Amendment Dated July 23, 2004
Reply to Office Action of August 27, 2003

to the skin for purposes of preventing or reducing the attachment of lauryl ether sulfate to the skin. As indicated above, it is not necessarily the case that a composition containing lauryl ether sulfate and N-acylamino acids was known based on Mager. Further, in view of Mager even if such compositions were known, it was *not* known whether such compositions were applied to human skin. Consequently, there's nothing in Mager that would have led a person of ordinary skill in the art to conclude that the instantly claimed method had been inherently practiced in the prior art.

With respect to the issue of inherency, it might be helpful for the Examiner to consider the decision in *In re Shetty*, 195 USPQ 753, 756-757 (CCPA 1977). The claims therein were drawn to a method of curbing appetite in animals by administering to the animals certain adamantane compounds. Certain similar compounds had previously been administered to animals, but for other purposes, i.e., to combat viral infections, to reduce blood sugar content and to treat depression. The Examiner therein reasoned that the claimed method was obvious because the compounds had previously been administered to animals in the same amount and, thus, the prior art technically taught the method step claimed.

The Court, in response, held that the *purpose* that is to be achieved is a factor to be considered in the obviousness of a claimed method of use. Thus, on pages 756-757, the Court comments:

"The issue here is whether the claimed method of curbing appetite would have been obvious. That appellant's 'amount effective to curb appetite' corresponds to

Page 12 of 15

Application No. 09/763,106
Amendment Dated July 23, 2004
Reply to Office Action of August 27, 2003

or inheres in Narayanan's amount 'to combat microbial infestation' does not persuade us of the obviousness of appellant's method. As this court said in *In re Naylor* [citations omitted]:

*[Inherency] is quite immaterial if, as the record establishes here, one of ordinary skill in the art would not appreciate or recognize that inherent result. ****

*** we find nothing in the record which would afford one of ordinary skill reason to anticipate that a trial *** [of the combined prior art teachings] would be successful in producing the polymer recited in the claims.

The Patent Office has failed to show a reasonable expectation, or some predictability, that Brake's compound *would be an effective appetite suppressant* if administered in the dosage disclosed by Narayanan. The mere hindsight assertion that corresponding dosages render appellant's method obvious is untenable. *Prior to appellant's disclosure, none of the adamantane compounds in any of the references suggested a use, much less a dosage, for curbing appetite.* What we said in *In re Spormann* [again, citations omitted], relative to inherency applies equally here:

*As we pointed out in *In re Adams* [citations omitted], the inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is*

Application No. 09/763,106
Amendment Dated July 23, 2004
Reply to Office Action of August 27, 2003

unknown (emphasis added)."

Given Mager, a person of ordinary skill in the art would have had no knowledge that N-acylamino acids and their salts prevent or reduce the attachment of lauryl ether sulfate during a washing process. Consequently, a person having ordinary skill in the art would not have been motivated by Mager to apply a lauryl ether sulfate in combination with N-acylamino acids and their salts to human skin for the purpose of preventing or reducing the attachment of lauryl ether sulfate to human skin.

In view of the foregoing, Applicants submit that the Examiner would be fully justified to reconsider and to withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is, therefore, earnestly solicited.

Conclusion

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.